

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/008235

International filing date (day/month/year)
21.07.2004

Priority date (day/month/year)
24.07.2003

International Patent Classification (IPC) or both national classification and IPC
A61M15/00

Applicant
GLAXO GROUP LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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IAP20 Rec'd PCT/PTO 23 JAN 2006

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2004/008235

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/008235

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/008235

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 69

because:

- ☒ the said international application, or the said claims Nos. 69 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 69
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/008235

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☒ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-68,70-72

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	5,6,8,10-31,33-39,41-46,48,50,52,53,57-59,70-72
	No: Claims	1-4,7,9,32,40,47,49,51,54-56,60-68
Inventive step (IS)	Yes: Claims	5,6,10-31,33,41-47,50,52,53,57-59
	No: Claims	1-4,7-9,32,34-36,38-40,47-49,51,54-56,60-68,70-72
Industrial applicability (IA)	Yes: Claims	1-68,70-72
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/008235

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)
and / or
2. Non-written disclosures (Rules 43*bis*.1 and 70.9)
see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

IAP20 Rec'd PCT/PTO 23 JAN 2006

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/008235

1 Concerning Item III

In the light of the description, the medicament dispenser can only be used for dispensing a medicament to a patient. Consequently, the subject-matter of claim 69 is considered to fall under Article 67.1(iv) PCT and will not be examined any further in respect of novelty and inventive step.

2 Concerning Item IV

In the light of WO-A-01/17595 (D1) the subject-matter of claim 1 is not novel (see Point 3.1). Consequently, claim 1 cannot have any special technical features as required by Rule 13.2 PCT. Thus, claims 1 and 70 cannot have any common or corresponding special technical features. Therefore, claims 1 and 70 do not meet the requirements of Rule 13 PCT.

In the light of the above, the present set of claims is considered to relate to two possible inventions being covered by the following groups of claims:

- (I) claims 1-68 and
- (ii) claims 70-72.

3 Concerning Item V

- 3.1 D1 discloses a medicament dispenser for plural elongate continuous loop (annular) form medicament carriers, comprising a receiving station (106), a release (5, 17), an outlet (implicit), an indexer (107, 108, 111), and two (annular) continuous loop medicament carriers (14, 16) as defined in claim 1. Thus, the subject-matter of claim 1 does not meet the requirement of Article 33(2) PCT.
- 3.2 In addition, the technical features of dependent claims 2-4, 7, 9, 32, 37, 40, 47, 49, 51, 54-56 and 60-68 appear to be disclosed by D1. Thus, said claims do not meet the requirement of Article 33(2) PCT.
- 3.3 The technical features of the remaining dependent claims 8, 34-36, 38, 39 and 48 are considered to relate either to a minor constructional change that can be realized by the skilled person or to one of several straightforward possibilities from which the skilled person could select, in accordance with the circumstances, without the exercise of inventive skills. Consequently, the subject-matters of said claims do not

appear to meet the requirement of Article 33(3) PCT.

- 3.4 The technical features of the remaining dependent claims 5, 6, 10-31, 33, 41-47, 50, 52, 53 and 57-59 do not appear to be derivable from any of the cited documents in an obvious manner. thus, said claims appear to meet the requirements of Article 33(2) and (3) PCT.
- 3.5 The subject-matter of claim 70 is considered to differ from the disclosure of D1 by that the dispenser further comprises a movable cover that couples to the dispensing mechanism such that movement of said cover actuates one or more components of the dispensing mechanism. WO-A-01/26720 (D2) discloses a medicament dispenser comprising such a cover (16, 236). Because D1 remains silent about the details of the inhaler and actuation mechanism, the skilled person would have to look for suitable solutions. Consequently, in the light of the disclosure and teaching of D2, the skilled person would appear to arrive at the subject-matter of claim 70. Furthermore, in that case the skilled person would appear to inevitably arrive also to the subject-matters of claims 71 and 72. Thus, said claims do not appear to meet the requirement of Article 33(3) PCT.
- 3.6 The industrial applicability (Article 33(4) PCT) of a device according to the claims 1-68 and 70-72 is self-evident.

4 Concerning Item VI

- 4.1 WO-A-03/61743 (D3, see Figs. 19 and 20), claiming a priority date being before the priority date of the preset application, but being published after the claimed priority date of the present application, appears to disclose a medicament dispenser which falls under the wordings of claims 1 and 70. In addition, D2 appears to disclose the technical features of dependent claims 2-33, 37 and 39-68.
- 4.2 Furthermore, WO-A-2004/011070 (D4) and WO-A-03/095010 (D5), claiming a priority date being before the priority date of the preset application, but being published after the claimed priority date of the present application, appear to disclose a medicament dispenser that falls under the wording of claim 70.
- 4.3 The attention of the applicant is drawn to the fact that in the regional phase said

documents may be considered as prior art.

5 Concerning Item VII

The closest prior art (D1) has not been identified as required by Rule 5(a)(ii) PCT. Furthermore, the independent claims are not in the two-part form as required by Rule 6.3(b) PCT. In addition, the claims do not include reference signs in parentheses as required by Rule 6.2(b) PCT.